

### REMARKS

This responds to the Office Action mailed on September 22, 2006.

Claim 111 is amended, no claims are canceled, and no claims are added; as a result, claims 63-79, 81-108, 111-112 and 117-121 are now pending in this application.

#### §112 Rejection of the Claims

Claim 111 was rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants thank the Examiner for pointing out this potential discrepancy. Claim 111 have been amended to recite "or" instead of "and", before the terms "mixtures thereof", as suggested by the Examiner.

#### §103 Rejection of the Claims

Claims 63-79, 81-108, 111-112 and 117-121 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085). This rejection is respectfully traversed.

The Examiner concluded the Office Action by stating that Applicants have failed to establish that the claimed compositions yield unexpected results relative to the teachings of the documents relied upon by the Examiner. Applicants respectfully request that the Examiner consider the following clarifications and remarks with respect to the claimed invention. The comparative studies discussed in the Gunatillake Declaration compare composition 1 (of Example 1) of the instant application, which includes an 'amine chain extender', with a composition falling within the scope of WO 98/13405, which is identical to composition 1 (of Example 1) of the instant application except that no amine siloxane chain extender (BATD) is present. By making the correct comparison, Applicants believe the Examiner will see that the Gunatillake Declaration does in fact support a showing of unexpected results for the claimed compositions. Reconsideration of the Gunatillake Declaration is respectfully requested.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not establish a *prima facie* case, the Applicant is under no obligation to submit evidence of non-obviousness. M.P.E.P. §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or

motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. M.P.E.P. §2142.

In the Office Action the Examiner conceded that none of the primary documents (Szycher '627, WO 98/13405, and JP 4-248826) "disclose the specific use of an amine functional siloxane as a chain extender and WO 98/13405 fails to disclose the use of an amine functional siloxane soft segment" (Official Action, page 3). However, the Examiner asserts that Li et al. '724 disclose the use of amine functional polysiloxane compounds which overlap Applicants' claimed soft and hard segment compounds in the production of biocompatible polyureas and polyurethane-ureas. In addition, the Examiner asserts that Ohtaki discloses amino functional tetraorganodisiloxanes as reactants with polyurethanes.

Szycher et al. U.S. 5,863,627 ( the '627 patent): as noted above, the Examiner acknowledges that there is no mention of the use of amine functional siloxanes as chain extenders in the '627 patent. The chain extenders disclosed are short diamines of diols (see column 4, lines 59-67.), *i.e.*, non-siloxanes, conventional in the polyurethane art. As discussed above, the use of a bis-amine terminated siloxane as a chain extender in the hard segment is not disclosed or suggested in the disclosure of the '627 patent. With respect to claim 104, the use of a low molecular weight bis-amine terminated bis- to tetra- siloxane in the hard segment is also not disclosed or suggested by Szycher et al. The Gunitillake Declaration also supports the fact that the incorporation of a bis-amine terminated siloxane as a chain extender has a significant impact on the mechanical properties of the polyurethane urea.

JP 4-248826 (abstract): Based on the information in the abstract, the amine functional siloxanes disclosed are used only in the soft segment in these formulations and not as a component in the hard segment. Again, this document fails to disclose the use of an amine functional siloxane as a chain extender in a polyurethane urea. The Gunitillake Declaration is again supportive of the impact that the presence of a bis-amine terminated siloxane as a chain extender has on the mechanical properties on the polyurethane urea.

WO 98/13405: This commonly-assigned document also fails to disclose the use of amine functional siloxanes as chain extenders in the hard segment (claims 104). Furthermore, there is

no teaching or suggestion of the use of bis-amine terminated siloxanes in both the hard and soft segments of polyurethanes as recited by claim 1.

Li et al. U.S. 5,221,724 (the '724 patent): The '724 patent discloses soft segments formed from a diisocyanate and a bis-amine terminated siloxane having 2-201 silicon atoms. Hard segments are formed from chain extended diisocyanates using conventional alkyl- or aryl-diols, or alkyl- or aryl-diamines as chain extenders. However, there is no teaching or suggestion to use amine terminated siloxanes of selected molecular weights to form both soft and hard segment components within the same polyurethane structure or to use bis-amine terminated disiloxane which contains 1-4 silicon atoms in the hard segment. Thus, the '724 patent does not cure the deficiencies of any of the primary references. A review of its disclosure, even combined with the knowledge of Szycher, WO 98/13405, or JP 4-248826, would not permit one to arrive at the claimed compositions without the use of hindsight.

Ohtaki et al. U.S. 5,861,085 (the '085 patent): This document discloses the use of amino functional tetraorganodisiloxane as a modifier for polyurethanes. However, there is no teaching or suggestion to use the amino functional disiloxanes in both the hard and soft segments of any polyurethane, or to use it only in the hard segment. Similarly, the '085 patent fails to cure or complete the deficiency of any of the primary documents and would not permit one to arrive at the claimed compositions.

Accordingly, none of the cited documents {Szycher '627, WO 98/13405, or JP 4-248826; each in view of Li '724 and Ohtaki '085}, alone or in any combination, disclose or suggest all of the elements of the presently claimed invention. Specifically, none of these documents disclose or suggest the use of an amine functional siloxane compound of formula (I) wherein  $n = 1$  to 4 as a chain extender in the hard segment, as in compositions of the present claims. Additionally, none of these documents disclose or suggest polyurethane-urea compositions where both the soft segment and the hard segment contain silicone-containing macrodiamine compounds ( $n = 5$  to 100 and  $n = 1-4$ ) as claimed in the present claims. It is respectfully submitted that the Examiner is employing hindsight to arrive at Applicant's invention by assembling it from isolated disclosures in the art. Without knowledge of Applicant's invention, there would be no motivation to use bis-amino terminated siloxanes disclosed in the secondary references to arrive at the claimed polyurethanes.

In particular, the Examiner's attention is directed to Example 1 which discloses a polyurethane urea consisting of amine functional siloxane segments forming a hard segment component and having a high tear strength. The Examiner's attention is also directed to Example 13 where the results of a sheep implant study exhibit the biostability and fatigue resistance of the polyurethane ureas of the present invention. Finally, Example 14 provides data on cyclic flex fatigue resistance which further illustrates the excellent fatigue resistance of the polyurethane ureas of the present invention. Applicants respectfully submit that these examples illustrate the unexpected advantages of the claimed polymers prepared using amine functional siloxanes in both the soft and hard segments to improve tear strength as well as fatigue resistance is not obvious from the cited references.

Even assuming, *arguendo*, that one of skill in the art in possession of the cited art would be motivated to prepare Applicants' polyurethane-urea elastomeric composition, the Examiner is respectfully reminded that if a composition has unique and unexpected properties, and there is nothing in the prior art to indicate that the composition would have such properties, the composition is not obvious in view of the prior art. In re Papesch, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963); In re Lunsford, 148 U.S.P.Q. 716 (C.C.P.A. 1966).

To rebut a *prima facie* case of obviousness, Applicants can submit evidence of unexpected results in the form of an affidavit or declaration under 37 C.F.R. §1.132. M.P.E.P. §716.02 (e), citing In re Burckel, 201 U.S.P.Q. 67 (C.C.P.A. 1979). The evidence relied upon by Applicants to establish unexpected results should demonstrate "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Id., citing Ex parte Gelles, 22 U.S.P.Q.2d 1318, 1319 (B.P.A I. 1992). Evidence of unexpected properties may be in the form of a direct or an indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. M.P.E.P. §716.02(b).

As evidence that Applicants' invention possesses unexpected properties, the Examiner is requested to consider the Declaration of Pathiraja Arachichillage Gunatillake, who is a named co-inventor on the present application, which was submitted with the previous Office Action response. In the Declaration, Pathiraja Arachichillage Gunatillake discusses the comparison of polymers of Example 1 of the instant specification to representative polymers of WO 98/13405

and Li et al. and concludes that the presently claimed polymers exhibit unexpectedly improved properties over those exemplified in the references.

Accordingly, it is respectfully submitted that the claimed invention is not obvious over the cited documents taken alone or in any combination. Applicants respectfully request withdrawal of the rejection of the present claims under 35 U.S.C. § 103(a) in light of applicants remarks above.

### **Reservation of Rights**

In the interest of clarity and brevity, Applicant may not have addressed every assertion made in the Office Action. Applicant's silence regarding any such assertion does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3270 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

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Date 3/22/2007

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**CERTIFICATE UNDER 37 CFR § 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22317-1450, on this 22<sup>nd</sup> day of March 2007.

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